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Attorneys for Plaintiff
Keryx Biopharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----- x
KERYX BIOPHARMACEUTICALS, INC.,

Plaintiff,

ECF CASE

- against -

07 Civ. 10376 (CSH)

PANION & BF BIOTECH, INC.,

DECLARATION OF
BETH LEVINE

Defendant.

----- x

1. I am Senior Vice President, General Counsel, Chief Compliance Officer and Corporate Secretary of Keryx Biopharmaceuticals, Inc. (“Keryx”), a position I have held since April 18, 2007. I make this declaration in support of Keryx’s motion for a preliminary injunction. I have personal knowledge of the matters set forth in this declaration, except as otherwise indicated.

2. Section 8.1.1 of the License Agreement dated November 7, 2005 between Keryx and Panion & BF Biotech, Inc. (“Panion”) states, in relevant part,

“Licensor shall use reasonable efforts to prosecute the patent applications included in the Patent Rights...Licensor shall be solely responsible for all costs and expense relating to such patent applications and patents. Licensor shall regularly consult with Licensee and shall keep Licensee advised of the status of all patent applications and patents relating to the Patent Rights by providing Licensee with all patent office correspondence relating thereto including any

office actions received by Lessor.... Lessor specifically agrees to provide Licensee with copies of patent office correspondence in sufficient time for Licensee to review and comment on such correspondence and submit to Lessor any proposed response thereto. Lessor further agrees to provide Licensee with sufficient time and opportunity, but in no event less than ten (10) days, to review, comment and consult an all proposed responses to patent office correspondence relating to such patent applications and patents. Licensee agrees that all final decisions regarding the preparation and prosecution of such patent applications and patents...shall be made by Lessor after consultation with Licensee. Notwithstanding the foregoing, Lessor shall have the right in its sole discretion after consultation with Licensee, to discontinue the prosecution of any such patent applications...and Licensee shall have the right to assume responsibility for the prosecution of such patent applications...of such patents at its own expense..."

(The License Agreement was filed under seal with the Court on November 19, 2007 as Exhibit 1 to the Declaration of Michael S. Weiss.)

3. On June 15, 1999, Panion filed in the Japanese Patent Office an application for a patent entitled "Method For Treating Renal Failure" (JP App. No. 10-527705) relating to the Licensed Product. That application is based on International Application No. PCT/US97/20977, whose applicant resides in the United States. See Exhibit 1 (identifying the applicant as a resident of Michigan). On August 28, 2007, the Japanese Patent Office issued a second notice of Office Action rejecting that patent application. A response to the notice of Office Action is presently due by November 28, 2007. Attached as part of Exhibit 8 is an English translation of that notice of Office Action.

4. Despite its obligation under the License Agreement to keep Keryx advised of all patent office correspondence, Panion did not notify Keryx of the Office Action at the time it was issued. Rather, repeated requests for updated patent dockets before and after the office action went unanswered by Panion. Indeed, although Keryx received a patent docket on September 5, 2007 from Panion's attorney, Michael Stanley, this patent docket did not reflect the August 28, 2007 office action. Attached as Exhibit 2 is Michael Stanley's email dated September 5, 2007.

5. Before granting an exclusive sublicense for Japan (the “Japanese Sublicense”) to Japan Tobacco, Inc. (“Japan Tobacco”) and Torii Pharmaceutical Co. Ltd. (“Torii”) in September, 2007, Keryx required an updated patent docket summary for the Japanese patent application, and on at least three occasions, requested such a docket. Attached as Exhibit 3 is my request in an email to Michael Chiang et al. dated September 18, 2007. Attached as Exhibit 4 is my request in an email to Michael Chiang et al. dated September 20, 2007. Attached as Exhibit 5 is my request in an email to Albert Wai-Kit Chan et al. dated September 21, 2007.

6. On September 21, 2007, Keryx received an update to the patent docket from Dr. Chan. This update, sent to me via email, is attached as Exhibit 6. The updated docket did not mention the Japanese Office Action dated August 28, 2007.

7. Keryx was first notified of the August 28, 2007 Office Action via email from Dr. Chan on October 1, 2007. Attached as Exhibit 7 is a copy of this email and the updated patent docket. The patent docket states that response to the Office Action is due November 28, 2007, and also states, “February 28, 2008: Response to Office Action due (abs deadline),” suggesting that Panion considered the availability and the likelihood of obtaining an extension of its time to respond to the Notice of Office Action.

8. An English translation of the August 28, 2007 Note of Office Action was not provided to Keryx until October 10, 2007, more than six weeks after the Notice of Office Action was issued. The email attaching this translated version of the Note of Office Action is attached as Exhibit 8.

9. On October 11, 2007, Dr. Chan sent to Keryx a draft response to the office action, which Keryx immediately forwarded to Japan Tobacco. The emails to Keryx attaching these drafts are attached as Exhibits 9 and 10.

10. To facilitate expeditious review of the Office Action and preparation of a response, Keryx requested that Panion permit Japan Tobacco to meet directly with Panion's Japanese patent counsel. On October 11, 2007, Dr. Chan sent an email to Mr. Toshio Takizawa, Panion's patent attorney in Japan, instructing him to discuss with Japan Tobacco and their counsel the best way to overcome the objections and rejections from the Japanese Patent Office. This email is attached as Exhibit 11.

11. On October 24, 2007, I received an email from Dr. Koshi Koseki, General Manager, Intellectual Property at Japan Tobacco reporting on a meeting that was held between Mr. Toshio Takizawa, Dr. Koshi Koseki and Japan Tobacco's outside patent counsel, Mr. Teruo Daito. This email is attached as Exhibit 12. It was reported to me that a ninety minute discussion was held at Mr. Takizawa's offices and that it was agreed that the next step would be for Japan Tobacco to conduct an additional search for information in the public domain to support patentability and that a future meeting would be held to discuss the results of that search and resulting strategy. In his email, Dr. Koseki asked Keryx to request that Panion seek a three-month extension of the deadline to response, noting, "Three months extension should be allowed if requested."

12. On October 24, 2007, Keryx sent an email to Dr. Chan, forwarding the email from Dr. Koseki and requesting that they seek a three-month extension of time to respond to the office action. Dr. Chan responded, "we will proceed as instructed and request a three month extension of time." Dr. Chan's email is attached as Exhibit 13.

13. On October 25, 2007, I received an email from Dr. Chan in which he stated that "Contrary to our below email [forwarding his October 24, 2007 email], we might not be able to carry out your recommendation based on the unresolved issues between Keryx and Panion."

This email is attached as Exhibit 14.

14. On October 26, 2007, I sent an email to Dr. Chan in which I expressed the view that Panion's refusal to seek the extension of time was wholly unjustified and was a bad faith attempt to link the patent extension request to unrelated contractual matters. This email is attached as Exhibit 15.

15. On October 31, 2007, I received an email from Dr. Chan stating that Panion had instructed their Japanese counsel not to communicate with any third party but Panion and declaring Keryx in material breach of the contract and threatening to nullify the agreement. This email is attached as Exhibit 16. Keryx had not previously received written notice under the License Agreement of any material breach.

16. After some further correspondence, on November 6, 2007, I sent an email to Dr. Chan expressing my dismay at the unreasonable position Panion was taking with respect to the Japanese patent prosecution and imploring him to seek the extension so that Japan Tobacco could complete their comprehensive search. This email is attached as Exhibit 17. In that email I offered to assume any additional expenses incurred as result of the request for extension.

17. On November 6, 2007, I sent an email to Dr. Koseki asking him to send me his substantive comments on the draft response as well as any results from Japan Tobacco's search, even though I understood that the search was not yet complete. Later that day, I received a response from Dr. Koseki in which he advised me that the search was far from complete and that without article support it might be difficult to overcome the office action, as inventor's declarations do not carry as much weight in Japan. These emails are attached as Exhibit 18.

18. On November 8, 2007, Dr. Chan sent me an email expressing surprise that Japan Tobacco's search had not been concluded in the fourteen days that had passed since their

meeting with Panion's counsel. This email is attached as Exhibit 19.

19. On November 12, 2007, I received from Dr. Koseki a status report and summary of their search, which had yielded over 3000 references that needed to be fully analyzed. This email is attached as Exhibit 20. By that date, less than half of this work had been completed. Keryx forwarded this information to Dr. Chan on November 12, 2007.

20. On November 17, 2007, faced with the continuing unreasonableness of Panion in refusing to seek an extension, I asked Japan Tobacco to provide me with whatever references their search had yielded to date so that Dr. Chan would have the benefit of Japan Tobacco's work in preparing the response that was due ten days hence. This email is attached as Exhibit 21.

21. On November 19, 2007, Dr. Koseki provided me with six references. However, as he explained in his email, an extension was necessary because "the background of the technology [for support of the Japanese patent application] is so broad" and therefore, the search had produced a large number of results to be analyzed. His email was divided into two separate emails; part one is attached as Exhibit 22* and part two is attached as Exhibit 23*.

22. On November 19, 2007, I forwarded those references to Dr. Chan, stressing that the search was incomplete and that without a complete search, Panion was increasing the risk of an unfavorable decision from the Japanese Patent Office. This email is attached as Exhibit 24*. I have not received any response to that email. To date, I have not seen any draft response to the office action since the first draft provided on October 11, 2007.

*Exhibits 22, 23, 24 to this Declaration have been redacted to protect the attorney-client privilege.

I, BETH LEVINE, hereby declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge and belief.

Dated: November 20, 2007



Beth Levine

Exhibit 1

to Declaration of Beth Levine



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 31/295	A1	(11) International Publication Number: WO 98/26776 (43) International Publication Date: 25 June 1998 (25.06.98)
(21) International Application Number: PCT/US97/20977		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 14 November 1997 (14.11.97)		
(30) Priority Data: 60/032,745 16 December 1996 (16.12.96) US 08/794,328 3 February 1997 (03.02.97) US		
(71)(72) Applicant and Inventor: HSU, Chen, Hsing [US/US]; 3720 Tremont Drive, Ann Arbor, MI 48105 (US).		
(74) Agents: SMITH, DeAnn, F. et al.; Harness, Dickey & Pierce, P.L.C., P.O. Box 828, Bloomfield Hills, MI 48303 (US).		
		Published <i>With international search report.</i>

(54) Title: METHOD FOR TREATING RENAL FAILURE

(57) Abstract

Methods of controlling phosphate metabolism and metabolic acidosis in patients suffering from renal failure and associated hyperphosphatemia or patients predisposed to development of a hyperphosphatemic condition are provided. The method in accordance with this invention comprises administering to a patient a ferric-containing compound selected from the group consisting of ferric citrate, ferric acetate, and combinations thereof. Therapeutic benefit can be realized in accordance with such method by administering the compound orally to a patient to contact and bind with ingested phosphate in the patient's digestive tract, and thereby prevent its intestinal absorption.

Exhibit 2

to Declaration of Beth Levine

From: Michael Stanley [mstanley@stanleyphillips.com]
Sent: Wednesday, September 05, 2007 2:46 PM
To: Levine, Beth [blevine@keryx.com]
Subject: RE: Follow-Up
Attachments: Patent Docket Summary Aug-30-07.doc

Beth:

Attached is a patent docket, as we discussed.

Although I have not received the consents from Panion and GloboAsia yet, I do not think it is going to be a problem. I hope to have a definitive answer, and consents, within the next day or two.

Michael

Michael J. Stanley
Stanley, Phillips & Rose, L.L.P.
1330 Post Oak Blvd., Suite 2820
Houston, Texas 77056
(713) 980-4381
(713) 980-1179 (fax)
mstanley@stanleyphillips.com

From: blevine@keryx.com [mailto:blevine@keryx.com]
Sent: Tuesday, September 04, 2007 9:55 AM
To: Michael Stanley
Subject: Follow-Up

Michael,

I hope you had an enjoyable Labor Day weekend. The weather here was gorgeous.

I am wondering if you've had any feedback from Panion or GloboAsia on the consent letters? Things are progressing as planned with our potential sublicensee and we need to respond to them on the matter of the consent letters. Your feedback is much appreciated.

Thanks. Beth

Beth Levine
Senior Vice President, General Counsel, Chief Compliance Officer & Corporate Secretary
Keryx Biopharmaceuticals, Inc.
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PATENT DOCKET SUMMARYAug-30-07
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PATENT DOCKET SUMMARYAug-30-07
(Draft)Patent Dkt#859 (KWOK et al., 2004)

DOCKET #	MATTER	NOTE
Dkt. #859-PCT	FERRIC ORGANIC COMPOUNDS, USES THEREOF AND METHODS OF MAKING SAME Int'l App'1 No. PCT/US2004/004646, Filed February 18, 2004, claiming priority of U.S. Serial No. 60/447,690, filed February 19, 2003 and U.S. Serial No. 60/462,684, filed April 15, 2003 Inventors: David W.K. KWOK and Nikolay Mintchev STOYNOV Applicant: GloboAsia	EXPIRED
Dkt. #859-PCT-CAN	FERRIC ORGANIC COMPOUNDS, USES THEREOF AND METHODS OF MAKING SAME Canadian App'1 No. 2,516,471, Filed August 18, 2005, National Stage App'1 of Int'l App'1 No. PCT/US2004/004646, filed February 18, 2004, claiming priority of U.S. Serial No. 60/447,690, filed February 19, 2003 and U.S. Serial No. 60/462,684, filed April 15, 2003 Inventors: David W.K. KWOK and Nikolay Mintchev STOYNOV Applicant: GloboAsia	PENDING
Dkt. #859-PCT-EPO	FERRIC ORGANIC COMPOUNDS, USES THEREOF AND METHODS OF MAKING SAME European App'1 No. 04712312.0, Filed September 13, 2005, National Stage App'1 of Int'l App'1 No. PCT/US2004/004646, filed February 18, 2004, claiming priority of U.S. Serial No. 60/447,690, filed February 19, 2003 and U.S. Serial No. 60/462,684, filed April 15, 2003 Inventors: David W.K. KWOK and Nikolay Mintchev STOYNOV Applicant: GloboAsia	PENDING
Dkt. #859-PCT-ERA	FERRIC ORGANIC COMPOUNDS, USES THEREOF AND METHODS OF MAKING SAME Eurasian App'1 No. 200501322, Filed September 19, 2005, National Stage App'1 of Int'l App'1 No. PCT/US2004/004646, filed February 18, 2004, claiming priority of U.S. Serial No. 60/447,690, filed February 19, 2003 and U.S. Serial No. 60/462,684, filed April 15, 2003 Inventors: David W.K. KWOK and Nikolay Mintchev STOYNOV Applicant: GloboAsia	PENDING

- June 30, 2006: Received “Assignment Recordal Certificates”
- March 17, 2006: Received “Notification of the Positive Result of Formal Examination and a Notification of Consideration of Request for Substantive Examination”
- May 02, 2007: Received “Notification of Conclusion on Patentability of the Invention 03.26.07”
- July 25, 2007: Replied ROA

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PATENT DOCKET SUMMARYAug-30-07
(Draft)

DOCKET #	MATTER	NOTE
Dkt. #859-PCT-IL	FERRIC ORGANIC COMPOUNDS, USES THEREOF AND METHODS OF MAKING SAME Israeli App'1 No. 170382, Filed August 18, 2005, National Stage App'1 of Int'l App'1 No. PCT/US2004/004646, filed February 18, 2004, claiming priority of U.S. Serial No. 60/447,690, filed February 19, 2003 and U.S. Serial No. 60/462,684, filed April 15, 2003 Inventors: David W.K. KWOK and Nikolay Mintchev STOYNOV Applicant: GloboAsia	PENDING ■ October 7, 2005: Received "Filing Receipt"
Dkt. #859-PCT-JP	FERRIC ORGANIC COMPOUNDS, USES THEREOF AND METHODS OF MAKING SAME Japanese App'1 No. 2006-503637, Filed August 18, 2005, National Stage App'1 of Int'l App'1 No. PCT/US2004/004646, filed February 18, 2004, claiming priority of U.S. Serial No. 60/447,690, filed February 19, 2003 and U.S. Serial No. 60/462,684, filed April 15, 2003 Inventors: David W.K. KWOK and Nikolay Mintchev STOYNOV Applicant: GloboAsia	PENDING ■ February 27, 2006: Received "Notification of Application Number" ■ September 22, 2006: Publication No. 2006-518391, Publication Date: August 10, 2006 ■ April 25, 2007: Filed "Request for Examination"
Dkt. #859-PCT-MX	FERRIC ORGANIC COMPOUNDS, USES THEREOF AND METHODS OF MAKING SAME Mexican App'1 No. PA/A/2005/008784, Filed August 18, 2005, National Stage App'1 of Int'l App'1 No. PCT/US2004/004646, filed February 18, 2004, claiming priority of U.S. Serial No. 60/447,690, filed February 19, 2003 and U.S. Serial No. 60/462,684, filed April 15, 2003 Inventors: David W.K. KWOK and Nikolay Mintchev STOYNOV Applicant: GloboAsia	PENDING ■ March 31, 2006: Filed "Declaration and Power of Attorney"

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PATENT DOCKET SUMMARYAug-30-07
(Draft)**Patent Dkt#859A (KWOK *et al.*, 2005)**

DOCKET #	MATTER	NOTE
Dkt. #859-A-PCT-US	FERRIC ORGANIC COMPOUNDS, USES THEREOF AND METHODS OF MAKING SAME U.S. Serial No. 11/206,981, Filed August 18, 2005, Continuation-In-Part application of Int'l App. No. PCT/US2004/004646, filed February 18, 2004, which claims the benefit of U.S. Serial Nos. 60/447,690, filed February 19, 2003 and 60/462,684, filed April 15, 2003	<ul style="list-style-type: none"> ■ February 15, 2006: Received "Notice of Publication of Application"; Publication No. US-2006-0020026-A1, Publication Date January 26, 2006 ■ March 30, 2007: Received "Office Action on March 05, 2007" ■ May 23, 2007: Received "Notice of Recordation of Assignment Document 05.16.2007" ■ July 3, 2007: Filed "Supplemental Information Disclosure Statement" ■ July 6, 2007: Filed "Communication in Response to the March 5, 2007 Office Action and Petition for Three Month Extension of Time" and "Supplemental Information Disclosure Statement" <p>Inventors: David W.K. KWOK and Nikolay Mintchev STOYNOV Applicant: David W.K. KWOK and Nikolay Mintchev STOYNOV</p>

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PATENT DOCKET SUMMARYAug-30-07
(Draft)Patent Dkt#859B (KWOK *et al.*, 2005)

DOCKET #	MATTER	NOTE
Dkt. #859-B-PRO	PHARMACEUTICAL-GRADE FERRIC ORGANIC COMPOUNDS, USES THEREOF AND METHODS OF MAKING SAME U.S. Serial No. 60/709,511, Filed August 19, 2005 Inventors: David W.K. KWOK and Nikolay Mintchev STOYNOV Applicant: David W.K. KWOK and Nikolay Mintchev STOYNOV	EXPIRED

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PATENT DOCKET SUMMARYAug-30-07
(Draft)Patent Dkt#1092 (HSU, 1997)

DOCKET #	MATTER	NOTE
Dkt. #1092-US	METHOD FOR TREATING RENAL FAILURE U.S. Serial No. App'1 08/794,328, Filed February 3, 1997, now Patent No. 5,753,706, issued May 19, 1998, claiming benefit of U.S. Serial No. 60/032,745, filed December 16, 1996 Inventor: Chen Hsing HSU	ISSUED
Dkt. #1092-PCT-CAN	METHOD FOR TREATING RENAL FAILURE Canadian App'1 No. 2,272,711, Filed May 26, 1999, National Stage App'1 of Int'l App'1 No. PCT/US97/20977, filed November 14, 1997, which is a continuation of U.S. Serial No. 08/794,328, filed February 3, 1997, and U.S. Serial No. 60/032,745, filed December 16, 1996 Applicant: Chen Hsing HSU	PENDING ■ February 6, 2006; Received "Office Action 12.22.05" ■ June 19, 2006; Filed "Response to Office Action 12.22.05" ■ October 6, 2006; Received "Office Action 09.15.06" ■ January 19, 2007; Filed "Response to Office Action 09.15.06"
Dkt. #1092-PCT-EPO	METHOD FOR TREATING RENAL FAILURE European App'1 No. 97948333.6, Filed November 14, 1997, National Stage App'1 of Int'l App'1 No. PCT/US97/20977, filed November 14, 1997, which is a continuation of U.S. Serial No. 08/794,328, filed February 3, 1997, and U.S. Serial No. 60/032,745, filed December 16, 1996 Applicant: Chen Hsing HSU	PENDING ■ July 19, 2006; Filed "Response to Second Examination Report 05.16.06"
Dkt. #1092-PCT-IL	METHOD FOR TREATING RENAL FAILURE Israeli App'1 No. 130041, Filed May 19, 1999, now Patent No. 130041, issued December 1, 2005, National Stage App'1 of Int'l App'1 No. PCT/US97/20977, filed November 14, 1997, which is a continuation of U.S. Serial No. 08/794,328, filed February 3, 1997, and U.S. Serial No. 60/032,745, filed December 16, 1996 Applicant: Chen Hsing HSU	ISSUED ■ March 17, 2006; Received "Certificate of Patent Grant"

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PATENT DOCKET SUMMARYAug-30-07
(Draft)

DOCKET #	MATTER	NOTE
Dkt. #1092-PCT-JP	METHOD FOR TREATING RENAL FAILURE Japanese App'1 No. 10-527705, Filed June 15, 1999, National Stage App'1 of Int'l App'1 No. PCT/US97/20977, filed November 14, 1997, which is a continuation of U.S. Serial No. 08/794,328, filed February 3, 1997, and U.S. Serial No. 60/032,745, filed December 16, 1996 Dkt. #1092-Z-PCT-JP (Divisional) Japanese App'1 No. 2007-133978, filed May 21, 2007 which is a divisional app'1 of Japanese App'1 No. 10-527705, Filed June 15, 1999, National Stage App'1 of Int'l App'1 No. PCT/US97/20977, filed November 14, 1997, which is a continuation of U.S. Serial No. 08/794,328, filed February 3, 1997, and U.S. Serial No. 60/032,745, filed December 16, 1996 Applicant: Chen Hsing HSU	PENDING <ul style="list-style-type: none">■ December 13, 2006: Received "Office Action 11.13.06"■ June 7, 2007: Filed "Response to Office Action"■ June 12, 2007: Received "Filed application"■ August 10, 2007: Received "Request for Examination" and claims need to be Amended to distinguish from parent patent application.
Dkt. #1092-PCT-MX	METHOD FOR TREATING RENAL FAILURE Mexican App'1 No. 9905595, Filed June 16, 1999, now Patent No. 2007250, issued March 19, 2002, National Stage App'1 of Int'l App'1 No. PCT/US97/20977, filed November 14, 1997, which is a continuation of U.S. Serial No. 08/794,328, filed February 3, 1997, and U.S. Serial No. 60/032,745, filed December 16, 1996 Applicant: Chen Hsing HSU	ISSUED
Dkt. #1092-PCT-NO	METHOD FOR TREATING RENAL FAILURE Norwegian App'1 No. 19992936, Filed June 16, 1999, National Stage App'1 of Int'l App'1 No. PCT/US97/20977, filed November 14, 1997, which is a continuation of U.S. Serial No. 08/794,328, filed February 3, 1997, and U.S. Serial No. 60/032,745, filed December 16, 1996 Applicant: Chen Hsing HSU	PENDING <ul style="list-style-type: none">■ May 02, 2007: Received "Office Action 01-15-07" and draft ROA■ July 5, 2007: Filed "ROA 07.03.07"

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PATENT DOCKET SUMMARYAug-30-07
(Draft)Patent Dkt#1098 (HSIAO et al., 2003)

DOCKET #	MATTER	NOTE
Dkt. #1098-US	PHARMACEUTICAL-GRADE FERRIC CITRATE U.S Serial No. 10/682,045, Filed October 8, 2003, now Patent No. 6,903,235, issued June 7, 2005 Inventors: Yih-Ming HSIAO, et. al. Assignee: Panion & BF Biotech	ISSUED

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Exhibit 3

to Declaration of Beth Levine

From: Levine, Beth [blevine@keryx.com]
Sent: Tuesday, September 18, 2007 11:46 AM
To: 'Michael Chiang'; 'wtown@globoasia.com'; 'kchan@globoasia.com'; Michael Stanley
Cc: Weiss, Michael S. [msw@keryx.com]; Hoberman, Ken [khoberman@keryx.com]
Subject: URGENT - IMMEDIATE ATTENTION REQUIRED
Importance: High

Gentlemen,

My name is Beth Levine and I am General Counsel of Keryx. As you know, we have an opportunity to significantly advance the development of ferric citrate in Japan through a proposed sublicense arrangement with Japan Tobacco and their pharmaceutical subsidiary Torii Pharmaceuticals. Beginning on August 22nd, and continuing via multiple contacts and attempted contacts through today, we have tried in good-faith to work through your attorney, Mr. Stanley, to obtain an updated and complete patent docket (as required under Section 8.1 of our license agreement) as well as to obtain your consent to the proposed transaction as requested by Japan Tobacco.

Throughout this time, I have repeatedly requested an updated patent docket and appropriate follow-up on the proposed consents. Although I received assurances that there were not expected to be any significant issues with the consents, I have just learned that Panion is not prepared to sign the consents as they are.

There are two issues that require your immediate attention.

First, it is imperative that we receive a complete and current patent docket from Panion by the close of business today, September 18th. I would ask that the patent attorney also advise us of any further action from the Japanese patent office in relation to the Response to Office Action that was filed on June 7, 2007. We are entitled to this information under Section 8.1 of the License Agreement and we must have it to include in the Sublicense Agreement that Japan Tobacco will present to their Executive Committee tomorrow.

Second, Japan Tobacco has requested the consents for two reasons – to ensure that they have the ability to support and defend the patents in Japan and to ensure that their rights to ferric citrate in Japan would not be adversely affected by a termination of the License Agreement between Panion and Keryx (or, in the case of GloboAsia, between GloboAsia and Panion as well). These requests are not unreasonable. If, in fact, there were a termination of the License Agreement between Panion and Keryx, the consents would grant Japan Tobacco no greater rights than Panion has already granted to Keryx. Japan Tobacco would simply step into the shoes of Keryx and Panion's right to receive royalties and milestone payments with respect to Japan would continue.

As you well know, Keryx has the right to sublicense its rights to ferric citrate without obtaining

prior consent from Panion or GloboAsia and if the consents are not forthcoming we will do our best to close the deal with Japan Tobacco without them. Even if we do close, I would expect that Japan Tobacco will continue to want the consents and the long-term viability of the relationship would remain in jeopardy without them.

Because the consents are important to Japan Tobacco and we believe that it is in the best interests of all concerned to do all that we can to ensure the development of ferric citrate in Japan, we would be willing to consider some financial payment to Panion upon execution of the deal with Japan Tobacco (perhaps partial acceleration of the Japanese approval milestone and your legal fees for reviewing the consents) in consideration of the execution of the consents (and the provision of the patent update), if we can resolve the outstanding issues today.

Please understand that we are trying to advance the development of ferric citrate in a very important market. We also believe the royalties payable to both Panion and Keryx can be significant if the sales projections of Japan Tobacco are realized. We believe that Japan Tobacco is a fantastic partner for this project and want to do everything we can to ensure that the deal is consummated and remains in place to ensure the commercialization of ferric citrate in Japan. If we can close this deal, the development of ferric citrate in Japan will be accelerated to the benefit of all involved.

I am available throughout the day to attempt to resolve this matter. In addition to my contact information below, I can also be reached on my cell phone at 646-644-8473.

Sincerely,

Beth Levine

Beth Levine
Senior Vice President, General Counsel, Chief Compliance Officer & Corporate Secretary
Keryx Biopharmaceuticals, Inc.
750 Lexington Avenue - 20th floor
New York, NY 10022
212-584-5740
212-531-5961 (fax)
blevine@keryx.com

Exhibit 4

to Declaration of Beth Levine

From: Levine, Beth [blevine@keryx.com]
Sent: Thursday, September 20, 2007 9:03 AM
To: Michael Chiang
Cc: Weiss, Michael S. [msw@keryx.com]; Hoberman, Ken [khoberman@keryx.com]; wtown@globoasia.com; kchan@globoasia.com; Michael Stanley
Subject: RE: URGENT - IMMEDIATE ATTENTION REQUIRED
Attachments: Consent Letter - Panion.DOC; Consent Letter - GloboAsia.DOC

Dear Michael,

Thank you very much for your response. We are pleased that Panion consents to our proposed sublicense to Japan Tobacco (JT). We believe that this is an excellent opportunity to develop and commercialize the compound in Japan.

I would like to confirm that your letter represents an agreement that you plan to sign the form of consent provided by JT. The key provision of the consent is that if, in the unlikely event where the Panion-Keryx license agreement were terminated earlier than the end of the term, then JT would have the right to step into our shoes and continue to develop and sell ferric citrate under the Panion-Keryx license without disruption. Panion would continue to have the right to pursue any breach claims against Keryx, but JT's ability to sell ferric citrate in Japan would be unaffected. I am sure you can understand that they would not want to spend millions of Yen developing the drug in Japan, only to lose their rights if something occurred between Panion-Keryx.

With respect to GloboAsia, while we completely understand that GloboAsia has licensed all their rights to you (and nobody is claiming otherwise), apparently under Japanese law there are certain things that only the patent holder (not any of their licensees) can do, such as apply for a patent term extension. Because of these laws, JT wants assurances directly from GloboAsia that they are willing to execute the necessary documents for Japan so that JT can get the full benefit of the patents. Additionally, for the same reasons outlined above, JT wants assurances that if in the unlikely event there was a termination of the license agreement between Panion and GloboAsia, that JT's rights to continue developing and commercializing ferric citrate in Japan would not be affected.

We realize that the requested consents are unexpected, but believe that they are reasonable and do not in anyway diminish your rights or increase your obligations under the license. They simply assure JT that if they are not in breach, then they can continue development without interruption despite any breaks in the chain of license relationships (GloboAsia-Panion-Keryx-JT). We also believe they are necessary to ensure that we develop a positive relationship with JT.

I hope that this explanation helps you to understand why we are asking for both your signature and GloboAsia's signature on the proposed consents. I have attached them again for your convenience.

Additionally, we have attempted to receive an updated docket from Mr. Wai-Kit Chan, but he has indicated that he needs your permission to do so. Can you please direct him to provide us with an updated docket and to be available to us for any questions we may have? As mentioned in my previous e-mail, we will pay all of his fees associated with this activity. We must have a current patent docket to be able to execute the sublicense agreement.

We are available for a conference call tonight to discuss this at your convenience.

Best regards,

Beth

Beth Levine
 Senior Vice President, General Counsel, Chief Compliance Officer & Corporate Secretary
 Keryx Biopharmaceuticals, Inc.
 750 Lexington Avenue - 20th floor
 New York, NY 10022
 212-584-5740
 212-531-5961 (fax)
 blevine@keryx.com

From: Michael Chiang [mailto:michaelchiang@pbf.com.tw]
Sent: Thursday, September 20, 2007 6:04 AM
To: Levine, Beth [blevine@keryx.com]; michaelchiang@pbf.com.tw
Cc: Weiss, Michael S. [msw@keryx.com]; Hoberman, Ken [khoberman@keryx.com]; wtown@globoasia.com; kchan@globoasia.com
Subject: Re: URGENT - IMMEDIATE ATTENTION REQUIRED

Dear Beth

Apologies for the late reply as I was attending a meeting out of the office. I have relayed the message through Michael Stanley that Panion do not intend to uphold any consent. We view Keryx as a good partner all along. The request for consent came to us in early September and prior to that we have no knowledge of what was happening. Since the first day we received such request, we have indicated that we are willing to do so which is still our current position. On the other hand, as far as GloboAsia is concerned, all the rights and responsibilities for those geographic areas listed in the Panion-Keryx Agreement, dated November 2005, has been assigned to Panion, and therefore GloboAsia is not in a position to consent on the sub-licensing. If GloboAsia has to consent, GloboAsia has expressed that they would only consent to Panion's consent and GloboAsia has to know the content of Panion's consent. This is the history and what I would like to use this email as a consent to Keryx to enter into further sub-licensing agreement with Japan Tobacco.

Best regards,

Michael Chiang
 Executive President
 Panion & BF Biotech Inc
 Tel: +866-2-2655-8698
 Fax: +866-2-2655-8318
 Email: michaelchiang@pbf.com.tw

--
Open WebMail Project (<http://openwebmail.org>)

----- Original Message -----

> **From:** blevine@keryx.com [mailto:blevine@keryx.com]
> **Sent:** Tuesday, September 18, 2007 11:46 PM
> **To:** Michael Chiang; wtown@globoasia.com; kchan@globoasia.com; Michael Stanley
> **Cc:** msw@keryx.com; khoberman@keryx.com
> **Subject:** URGENT - IMMEDIATE ATTENTION REQUIRED
> **Importance:** High
>
> Gentlemen,
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> My name is Beth Levine and I am General Counsel of Keryx. As you know, we have an opportunity to significantly advance the development of ferric citrate in Japan through a proposed sublicense arrangement with Japan Tobacco and their pharmaceutical subsidiary Torii Pharmaceuticals. Beginning on August 22nd, and continuing via multiple contacts and attempted contacts through today, we have tried in good-faith to work through your attorney, Mr. Stanley, to obtain an updated and complete patent docket (as required under Section 8.1 of our license agreement) as well as to obtain your consent to the proposed transaction as requested by Japan Tobacco.
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> Throughout this time, I have repeatedly requested an updated patent docket and appropriate follow-up on the proposed consents. Although I received assurances that there were not expected to be any significant issues with the consents, I have just learned that Panion is not prepared to sign the consents as they are.
>
> There are two issues that require your immediate attention.
>
> **First**, it is imperative that we receive a complete and current patent docket from Panion by the close of business today, September 18th. I would ask that the patent attorney also advise us of any further action from the Japanese patent office in relation to the Response to Office Action that was filed on June 7, 2007. We are entitled to this information under Section 8.1 of the License Agreement and we must have it to include in the Sublicense Agreement that Japan Tobacco will present to their Executive Committee tomorrow.
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> **Second**, Japan Tobacco has requested the consents for two reasons – to ensure that they have the ability to support and defend the patents in Japan and to ensure that their rights to ferric citrate in Japan would not be adversely affected by a termination of the License Agreement between Panion and Keryx (or, in the case of GloboAsia, between GloboAsia and Panion as well). These requests are not unreasonable. If, in fact, there were a termination of the License Agreement between Panion and Keryx, the consents would grant Japan Tobacco no greater rights than Panion has already granted to Keryx. Japan Tobacco would simply step into the shoes of Keryx and Panion's right to receive royalties and milestone payments with respect to Japan would continue.
>
> As you well know, Keryx has the right to sublicense its rights to ferric citrate without obtaining prior consent from Panion or GloboAsia and if the consents are not forthcoming we will do our best to close the deal with Japan Tobacco without them. Even if we do close, I would expect that Japan Tobacco will continue to want the consents and the long-term viability of the relationship would remain in jeopardy without them.

> Because the consents are important to Japan Tobacco and we believe that it is in the best interests of all concerned to do all that we can to ensure the development of ferric citrate in Japan, we would be willing to consider some financial payment to Panion upon execution of the deal with Japan Tobacco (perhaps partial acceleration of the Japanese approval milestone and your legal fees for reviewing the consents) in consideration of the execution of the consents (and the provision of the patent update), if we can resolve the outstanding issues today.

>

> Please understand that we are trying to advance the development of ferric citrate in a very important market. We also believe the royalties payable to both Panion and Keryx can be significant if the sales projections of Japan Tobacco are realized. We believe that Japan Tobacco is a fantastic partner for this project and want to do everything we can to ensure that the deal is consummated and remains in place to ensure the commercialization of ferric citrate in Japan. If we can close this deal, the development of ferric citrate in Japan will be accelerated to the benefit of all involved.

>

> I am available throughout the day to attempt to resolve this matter. In addition to my contact information below, I can also be reached on my cell phone at 646-644-8473.

>

> Sincerely,

>

> Beth Levine

>

>

> Beth Levine

> Senior Vice President, General Counsel, Chief Compliance Officer & Corporate Secretary

> Keryx Biopharmaceuticals, Inc.

> 750 Lexington Avenue - 20th floor

> New York, NY 10022

> 212-584-5740

> 212-531-5961 (fax)

> blevine@keryx.com

>

----- End of Original Message -----

DRAFT

September 5, 2007

Panion & BF Biotech, Inc.
7F, No. 325, Section 4
Chung Hsiao E. Road
Taipei, Taiwan
Republic of China
Attention: Michael C.M. Chiang
President and CEO

Re: License Agreement dated as of November 7, 2005

Dear Mr. Chiang:

Reference is hereby made to the following:

A. Dr. Chen Hsing Hsu is the owner of all rights to U.S. Patent No. 5,753,706 issued May 19, 1998 and entitled "Methods for Treating Renal Failure" (the "Hsu Patent Property") pursuant to an Agreement for the Reassignment of Intellectual Property, with a last-signed date of August 16, 2000 between him and the University of Michigan;

B. Dr. Hsu granted to Panion & BF Biotech, Inc. ("Panion") an exclusive sublicensable license throughout the world (except the People's Republic of China) to the Hsu Patent Property pursuant to a Patent License Agreement dated July 20, 2001 as amended pursuant to Amendment No. 1 thereto dated as of August 29, 2005;

C. GloboAsia, LLC ("GloboAsia") is the owner of all rights to the international patent applications number PCT/US2004/004646 filed 18 February 2004 and PCT/US2006/032385 filed 18 August 2006 entitled "Ferric Organic Compounds, Uses Thereof and Methods of Making Same" and "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same", respectively (the "GloboAsia Patent Property"), pursuant to an Assignment dated January 16, 2004 between GloboAsia and Panion, to which the named inventors therein had assigned all rights to the GloboAsia Patent Property;

D. GloboAsia granted to Panion an exclusive sublicensable license throughout the world (except China, Korea and all other countries in the Asian Pacific Region but including Japan) to the GlobaAsia Patent Property pursuant to an Exclusive License Agreement dated November 7, 2005;

Mr. Michael C.M. Chiang

_____, ___, 2007

Page 2

E. Panion granted to Keryx Biopharmaceuticals, Inc. ("Keryx") an exclusive sublicensable sublicense throughout the world (except China, Korea and all other countries in the Asian Pacific Region but including Japan) to the Patent Rights as defined therein including the Hsu Patent Property and the GloboAsia Patent Property (the "Patent Rights"), Licensor Development Data and Licensor Know-How (each as defined in the Keryx License) pursuant to a License Agreement dated as of November 7, 2005 (the "Keryx License"); and

F. Keryx is granting to Japan Tobacco Inc. and Torii Pharmaceuticals Co., Ltd. (collectively "Sublicensee") an exclusive sublicense for Japan to the Patent Rights pursuant to a Sublicense Agreement dated September _____, 2007 (the "Japan Sublicense").

To facilitate the Japan Sublicense, Keryx requests the following confirmations from Panion:

1. Panion hereby gives consent to Keryx to grant to Sublicensee the Japan Sublicense.

2. In the event that the Keryx License is terminated, Panion shall be deemed to have granted to Sublicensee a direct license with respect to the Patent Rights, Licensor Development Data and Licensor Know-How, for Japan, under the terms and conditions of the Keryx License, provided that Sublicensee (i) agrees to be bound to Panion under the terms and conditions of the Keryx License; and (ii) Sublicensee is not in material breach of the Japan Sublicense.

3. Panion acknowledges that Dr. Hsu and GloboAsia each have been or will be asked to enter into a separate letter agreement with Keryx, under which Dr. Hsu and GloboAsia have agreed or will agree to take all procedures necessary to obtain registration of the exclusive license of the Hsu Patent Property or the GloboAsia Patent Property, as the case may be as "Senyo Jisshiken," under which Sublicensee is designated as the licensee, in accordance with Article 77 of the Japanese Patent Law respectively within sixty (60) days after issuance or registration of the relevant patents, at Sublicensee's request and expense. Panion agrees to cooperate with Dr. Hsu and GloboAsia to the greatest extent possible in obtaining such registration and take such actions as Dr. Hsu or GloboAsia may reasonably request in connection therewith.

4. Panion acknowledges that Sublicensee is relying on the foregoing in entering into the Japan Sublicense and making a substantial investment which will benefit Panion in developing and commercializing products based on the Patent Rights (and Licensor Development Data and Licensor Know-How) and that, accordingly (i) Sublicensee shall be regarded as a third party beneficiary of this letter agreement entitled to enforce its provisions and (ii) this letter agreement may not be amended, waived, modified or terminated except upon the written agreement of Sublicensee.

Chen Hsing Hsu, M.D.

_____, ___, 2007

Page 3

Please confirm Panion's agreement to the foregoing by signing a copy of this letter and returning it to us.

Very truly yours,

Michael Weiss
Chief Executive Officer

AGREED:

Panion & BF Biotech, Inc.

By: _____
Michael C.M. Chiang

DRAFT

September 5, 2007

GloboAsia, LLC
11427 Potomac Oaks Drive
Rockville, MD 20850
Attention: Mr. Keith Chan

Re: Exclusive License Agreement dated November 7, 2005

Dear Mr. Chan:

Reference is hereby made to the following:

- A. GloboAsia, LLC ("GloboAsia") is the owner of all rights to the international patent applications number PCT/US2004/004646 filed 18 February 2004 and PCT/US2006/032385 filed 18 August 2006 entitled "Ferric Organic Compounds, Uses Thereof and Methods of Making Same" and "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same", respectively (the "Licensed Patent Property"), pursuant to an Assignment dated January 16, 2004 between GloboAsia and Panion & BF Biotech, Inc. ("Panion"), to which the named inventors therein had assigned all rights to the Licensed Patent Property;
- B. GloboAsia granted to Panion an exclusive sublicensable license throughout the world (except China, Korea and all other countries in the Asian Pacific Region but including Japan) to the Licensed Patent Property pursuant to an Exclusive License Agreement dated November 7, 2005 ("GloboAsia License Agreement");
- C. Panion granted to Keryx Biopharmaceuticals, Inc. ("Keryx") an exclusive sublicensable sublicense throughout the world (except China, Korea and all other countries in the Asian Pacific Region but including Japan) to the Licensed Patent Property pursuant to a License Agreement dated as of November 7, 2005 ("Keryx License Agreement"); and
- D. Keryx is granting to Japan Tobacco Inc. and Torii Pharmaceuticals Co., Ltd. (collectively "Sublicensee") an exclusive sublicense for Japan to the Licensed Patent Property pursuant to a Sublicense Agreement dated September , 2007 (the "Japan Sublicense").

Mr. Keith Chan

_____, ___, 2007

Page 2

To facilitate the Japan Sublicense, as well as other potential sublicensing arrangements, Keryx requests the following confirmations from you:

1. You give consent to Keryx to grant to Sublicensee the Japan Sublicense.
2. GloboAsia agrees to take all procedures necessary to: (i) obtain registration of the exclusive license of the Licensed Patent Property under Section 3.1 of the Japan Sublicense in Japan as a “Senyo Jisshiken,” under which Sublicensee is designated as the licensee, in accordance with Article 77 of the Japanese Patent Law within sixty (60) days after issuance or registration of the relevant patents, at Sublicensee’s request and expense, and (ii) fully secure Sublicensee’s right as a primary licensee in the field of nephrology in Japan until said registration of “Senyo Jisshiken.”
3. In the event that the GloboAsia License Agreement is terminated prior to expiration, then GloboAsia shall be deemed to have granted to Keryx a direct license with respect to the Licensed Patent Property throughout the Territory (as defined in the Keryx License Agreement), provided that Keryx (i) agrees to be bound to you under the terms and conditions of the GloboAsia License Agreement; and (ii) Keryx is not in material breach of the Keryx License Agreement.
4. In the event that both the GloboAsia License Agreement and the Keryx License Agreement are terminated prior to expiration, then GloboAsia shall be deemed to have granted to Sublicensee a direct license with respect to the Licensed Patent Property, for Japan, under the terms and conditions of the GloboAsia License Agreement, provided that Sublicensee (i) agrees to be bound to GloboAsia under the terms and conditions of the GloboAsia License Agreement; and (2) Sublicensee is not in material breach of the Japan Sublicense.
5. GloboAsia acknowledges that Sublicensee is relying on the foregoing in entering into the Japan Sublicense and making a substantial investment which will benefit GloboAsia in developing and commercializing products based on the Licensed Patent Property and that, accordingly (i) Sublicensee shall be regarded as a third party beneficiary of this letter agreement entitled to enforce its provisions and (ii) this letter agreement may not be amended, waived, modified or terminated except upon the written agreement of Sublicensee.

Chen Hsing Hsu, M.D.

_____, ___, 2007

Page 3

Please confirm GloboAsia's agreement to the foregoing by signing a copy of this letter and returning it to us.

Very truly yours,

Michael Weiss
Chief Executive Officer

AGREED:

GloboAsia, LLC

By: _____
Keith Chan

Exhibit 5

to Declaration of Beth Levine

From: Levine, Beth [blevine@keryx.com]
Sent: Friday, September 21, 2007 8:56 AM
To: 'chank@kitchanlaw.com'
Cc: Weiss, Michael S. [msw@keryx.com]
Subject: FW: Dkt #855-PANION - telephone call
Importance: High
Attachments: Re: URGENT - IMMEDIATE ATTENTION REQUIRED; Consent Letter - Panion.DOC; Consent Letter - GloboAsia.DOC

Tracking:	Recipient	Delivery	Read
	'chank@kitchanlaw.com'		
	Weiss, Michael S. [msw@keryx.com]	Delivered: 9/21/2007 8:56 AM	Read: 9/21/2007 9:13 AM
	Hoberman, Ken [khoberman@keryx.com]	Delivered: 9/21/2007 8:56 AM	Read: 9/21/2007 9:11 AM
	Stier, Mark [mstier@keryx.com]	Delivered: 9/21/2007 8:56 AM	Read: 9/21/2007 9:04 AM

Mr. Wai-Kit Chan,

My name is Beth Levine and I am General Counsel of Keryx. I understand from an e-mail I received from Michael Chiang that you are now representing Panion in all matters relating to the Keryx/Panion License Agreement (I have attached that e-mail above). I assume, based on this e-mail, that you are now free to speak with us directly. As you will have read from the e-mail from Mr. Chiang, there are several urgent matters outstanding that require immediate attention. I would like to meet with you today to resolve the following matters:

1. We urgently require an updated patent docket. The patent docket that was sent through to us from Panion's prior counsel, Michael Stanley, did not include PCT/US2006/032385. We must have an updated docket today that includes all of the patents and patent applications, as well as any new developments since the last patent docket, which was dated August 30, 2007.
2. We need to obtain signatures from both Panion and GloboAsia on the draft consents that had been previously provided and which are attached again for your reference. The rationale for these documents is explained in the attached e-mail. Based on Michael Chiang's e-mails and representations from Michael Stanley, we assured JT that this was not a problem and that the consents would be signed. They have gone to their Executive Committee with that representation and it would be a great dishonor and embarrassment to our Japanese colleagues if they misrepresent to their Executive Committee, which would consequently seriously jeopardize the relationship and our ability to credibly work with them going forward.

I realize that you have just recently been brought into the business aspects of this matter and I would like the opportunity to discuss this with you in person to resolve any confusion or misunderstandings. Our CEO, Michael Weiss, and I would be happy to come to your office today to meet with you. In fact, Michael also went to Columbia Law School and thought your

name sounded familiar. Were you classmates?

I am in the office now and am free to meet with you at any time. Please respond as soon as possible.

Regards, Beth

Beth Levine
Senior Vice President, General Counsel, Chief Compliance Officer & Corporate Secretary
Keryx Biopharmaceuticals, Inc.
750 Lexington Avenue - 20th floor
New York, NY 10022
212-584-5740
212-531-5961 (fax)
blevine@keryx.com

From: Genovesi, Lina [lgenovesi@keryx.com]
Sent: Tuesday, September 18, 2007 3:52 PM
To: Levine, Beth [blevine@keryx.com]
Subject: FW: Dkt #855-PANION - telephone call

See below.

From: chank [mailto:chank@kitchanlaw.com]
Sent: Tuesday, September 18, 2007 3:43 PM
To: Genovesi, Lina [lgenovesi@keryx.com]
Cc: chank
Subject: Dkt #855-PANION - telephone call

Dear Lina,

I understand that you have called my cell phone today requesting to speak with me. Further, I also understand that you tried to reach me at my office today. I am currently asking for permission from my client to speak with you. Unfortunately, until I get permission, my standing instructions are still in force – I cannot speak with anyone from Keryx without instructions.

I apologize for the inconvenience and will attempt to get back to you as soon as possible.

Please acknowledge receipt of this e-mail.

Sincerely,

Albert Wai-Kit Chan, Ph.D. /ah
Law Offices of Albert Wai-Kit Chan, PLLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357
Tel: (718) 799-1000
Fax: (718) 357-8615

E-mail: chank@kitchanlaw.com

The information transmitted herein is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of, or taking any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited. If you received this in error, please contact the sender and delete the material from any computer. Thank you for your cooperation.

Speier, Ross

From: michaelchiang [michaelchiang@pbf.com.tw]
Sent: Friday, September 21, 2007 2:01 AM
To: Levine, Beth [blevine@keryx.com]
Cc: 江總; Weiss, Michael S. [msw@keryx.com]; Hoberman, Ken [khoberman@keryx.com]; wtown@globoasia.com; Keich Chan; 'chank'
Subject: Re: URGENT - IMMEDIATE ATTENTION REQUIRED

Dear Beth,

I wish to take this opportunity to let Keryx know that Albert Wai-Kit Chan will be representing us from this point on. He is also copied in this email.

Best,

Michael Chiang
Executive President
Panion & BF Biotech Inc

----- Original Message -----

From: blevine@keryx.com
To: [Michael Chiang](mailto:michaelchiang@pbf.com.tw)
Cc: msw@keryx.com ; khoberman@keryx.com ; wtown@globoasia.com ; kchan@globoasia.com ; Michael Stanley
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Cc: Weiss, Michael S. [mailto:msw@keryx.com]; Hoberman, Ken [mailto:khoberman@keryx.com]; wtown@globoasia.com; kchan@globoasia.com
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Dear Beth

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Michael Chiang
Executive President
Panion & BF Biotech Inc
Tel: +866-2-2655-8698
Fax: +866-2-2655-8318
Email: michaelchiang@pbf.com.tw

--
Open WebMail Project (<http://openwebmail.org>)

----- Original Message -----

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> **Second**, Japan Tobacco has requested the consents for two reasons – to ensure that they have the ability to support and defend the patents in Japan and to ensure that their rights to ferric citrate in Japan would not be adversely affected by a termination of the License Agreement between Panion and Keryx (or, in the case of GloboAsia, between GloboAsia and Panion as well). These requests are not unreasonable. If, in fact, there were a termination of the License Agreement between Panion and Keryx, the consents would grant Japan Tobacco no greater rights than Panion has already granted to Keryx. Japan Tobacco would simply step into the shoes of Keryx and Panion's right to receive royalties and milestone payments with respect to Japan would continue.

>
> As you well know, Keryx has the right to sublicense its rights to ferric citrate without obtaining prior consent from Panion or GloboAsia and if the consents are not forthcoming we will do our best to close the deal with Japan Tobacco without them. Even if we do close, I would expect that Japan Tobacco will continue to want the consents and the long-term viability of the relationship would remain in jeopardy without them.

>
> Because the consents are important to Japan Tobacco and we believe that it is in the best interests of all concerned to do all that we can to ensure the development of ferric citrate in Japan, we would be willing to consider some financial payment to Panion upon execution of the deal with Japan Tobacco (perhaps partial acceleration of the Japanese approval milestone and your legal fees for reviewing the consents) in consideration of the execution of the consents (and the provision of the patent update), if we can resolve the outstanding issues today.

>
> Please understand that we are trying to advance the development of ferric citrate in a very important market. We also believe the royalties payable to both Panion and Keryx can be significant if the sales projections of Japan Tobacco are realized. We believe that Japan Tobacco is a fantastic partner for this project and want to do everything we can to ensure that the deal is consummated and remains in place to ensure the commercialization of ferric citrate in Japan. If we can close this deal, the development of ferric citrate in Japan will be accelerated to the benefit of all involved.

>
> I am available throughout the day to attempt to resolve this matter. In addition to my contact information below, I can also be reached on my cell phone at 646-644-8473.

>
> Sincerely,

>
> Beth Levine
>

>
> Beth Levine
> Senior Vice President, General Counsel, Chief Compliance Officer & Corporate Secretary
> Keryx Biopharmaceuticals, Inc.
> 750 Lexington Avenue - 20th floor
> New York, NY 10022
> 212-584-5740
> 212-531-5961 (fax)
> blevine@keryx.com

>
----- End of Original Message -----

DRAFT

September 5, 2007

Panion & BF Biotech, Inc.
7F, No. 325, Section 4
Chung Hsiao E. Road
Taipei, Taiwan
Republic of China
Attention: Michael C.M. Chiang
President and CEO

Re: License Agreement dated as of November 7, 2005

Dear Mr. Chiang:

Reference is hereby made to the following:

A. Dr. Chen Hsing Hsu is the owner of all rights to U.S. Patent No. 5,753,706 issued May 19, 1998 and entitled "Methods for Treating Renal Failure" (the "Hsu Patent Property") pursuant to an Agreement for the Reassignment of Intellectual Property, with a last-signed date of August 16, 2000 between him and the University of Michigan;

B. Dr. Hsu granted to Panion & BF Biotech, Inc. ("Panion") an exclusive sublicensable license throughout the world (except the People's Republic of China) to the Hsu Patent Property pursuant to a Patent License Agreement dated July 20, 2001 as amended pursuant to Amendment No. 1 thereto dated as of August 29, 2005;

C. GloboAsia, LLC ("GloboAsia") is the owner of all rights to the international patent applications number PCT/US2004/004646 filed 18 February 2004 and PCT/US2006/032385 filed 18 August 2006 entitled "Ferric Organic Compounds, Uses Thereof and Methods of Making Same" and "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same", respectively (the "GloboAsia Patent Property"), pursuant to an Assignment dated January 16, 2004 between GloboAsia and Panion, to which the named inventors therein had assigned all rights to the GloboAsia Patent Property;

D. GloboAsia granted to Panion an exclusive sublicensable license throughout the world (except China, Korea and all other countries in the Asian Pacific Region but including Japan) to the GlobaAsia Patent Property pursuant to an Exclusive License Agreement dated November 7, 2005;

Mr. Michael C.M. Chiang

_____, ___, 2007

Page 2

E. Panion granted to Keryx Biopharmaceuticals, Inc. ("Keryx") an exclusive sublicensable sublicense throughout the world (except China, Korea and all other countries in the Asian Pacific Region but including Japan) to the Patent Rights as defined therein including the Hsu Patent Property and the GloboAsia Patent Property (the "Patent Rights"), Licensor Development Data and Licenser Know-How (each as defined in the Keryx License) pursuant to a License Agreement dated as of November 7, 2005 (the "Keryx License"); and

F. Keryx is granting to Japan Tobacco Inc. and Torii Pharmaceuticals Co., Ltd. (collectively "Sublicensee") an exclusive sublicense for Japan to the Patent Rights pursuant to a Sublicense Agreement dated September ___, 2007 (the "Japan Sublicense").

To facilitate the Japan Sublicense, Keryx requests the following confirmations from Panion:

1. Panion hereby gives consent to Keryx to grant to Sublicensee the Japan Sublicense.
2. In the event that the Keryx License is terminated, Panion shall be deemed to have granted to Sublicensee a direct license with respect to the Patent Rights, Licensor Development Data and Licenser Know-How, for Japan, under the terms and conditions of the Keryx License, provided that Sublicensee (i) agrees to be bound to Panion under the terms and conditions of the Keryx License; and (ii) Sublicensee is not in material breach of the Japan Sublicense.
3. Panion acknowledges that Dr. Hsu and GloboAsia each have been or will be asked to enter into a separate letter agreement with Keryx, under which Dr. Hsu and GloboAsia have agreed or will agree to take all procedures necessary to obtain registration of the exclusive license of the Hsu Patent Property or the GloboAsia Patent Property, as the case may be as "Senyo Jisshiken," under which Sublicensee is designated as the licensee, in accordance with Article 77 of the Japanese Patent Law respectively within sixty (60) days after issuance or registration of the relevant patents, at Sublicensee's request and expense. Panion agrees to cooperate with Dr. Hsu and GloboAsia to the greatest extent possible in obtaining such registration and take such actions as Dr. Hsu or GloboAsia may reasonably request in connection therewith.
4. Panion acknowledges that Sublicensee is relying on the foregoing in entering into the Japan Sublicense and making a substantial investment which will benefit Panion in developing and commercializing products based on the Patent Rights (and Licensor Development Data and Licenser Know-How) and that, accordingly (i) Sublicensee shall be regarded as a third party beneficiary of this letter agreement entitled to enforce its provisions and (ii) this letter agreement may not be amended, waived, modified or terminated except upon the written agreement of Sublicensee.

Chen Hsing Hsu, M.D.

_____, ___, 2007

Page 3

Please confirm Panion's agreement to the foregoing by signing a copy of this letter and returning it to us.

Very truly yours,

Michael Weiss
Chief Executive Officer

AGREED:

Panion & BF Biotech, Inc.

By: _____
Michael C.M. Chiang

DRAFT

September 5, 2007

GloboAsia, LLC
11427 Potomac Oaks Drive
Rockville, MD 20850
Attention: Mr. Keith Chan

Re: Exclusive License Agreement dated November 7, 2005

Dear Mr. Chan:

Reference is hereby made to the following:

- A.** GloboAsia, LLC ("GloboAsia") is the owner of all rights to the international patent applications number PCT/US2004/004646 filed 18 February 2004 and PCT/US2006/032385 filed 18 August 2006 entitled "Ferric Organic Compounds, Uses Thereof and Methods of Making Same" and "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same", respectively (the "Licensed Patent Property"), pursuant to an Assignment dated January 16, 2004 between GloboAsia and Panion & BF Biotech, Inc. ("Panion"), to which the named inventors therein had assigned all rights to the Licensed Patent Property;
- B.** GloboAsia granted to Panion an exclusive sublicensable license throughout the world (except China, Korea and all other countries in the Asian Pacific Region but including Japan) to the Licensed Patent Property pursuant to an Exclusive License Agreement dated November 7, 2005 ("GloboAsia License Agreement");
- C.** Panion granted to Keryx Biopharmaceuticals, Inc. ("Keryx") an exclusive sublicensable sublicense throughout the world (except China, Korea and all other countries in the Asian Pacific Region but including Japan) to the Licensed Patent Property pursuant to a License Agreement dated as of November 7, 2005 ("Keryx License Agreement"); and
- D.** Keryx is granting to Japan Tobacco Inc. and Torii Pharmaceuticals Co., Ltd. (collectively "Sublicensee") an exclusive sublicense for Japan to the Licensed Patent Property pursuant to a Sublicense Agreement dated September , 2007 (the "Japan Sublicense").

Mr. Keith Chan

_____, ___, 2007

Page 2

To facilitate the Japan Sublicense, as well as other potential sublicensing arrangements, Keryx requests the following confirmations from you:

1. You give consent to Keryx to grant to Sublicensee the Japan Sublicense.
2. GloboAsia agrees to take all procedures necessary to: (i) obtain registration of the exclusive license of the Licensed Patent Property under Section 3.1 of the Japan Sublicense in Japan as a “Senyo Jisshiken,” under which Sublicensee is designated as the licensee, in accordance with Article 77 of the Japanese Patent Law within sixty (60) days after issuance or registration of the relevant patents, at Sublicensee’s request and expense, and (ii) fully secure Sublicensee’s right as a primary licensee in the field of nephrology in Japan until said registration of “Senyo Jisshiken.”
3. In the event that the GloboAsia License Agreement is terminated prior to expiration, then GloboAsia shall be deemed to have granted to Keryx a direct license with respect to the Licensed Patent Property throughout the Territory (as defined in the Keryx License Agreement), provided that Keryx (i) agrees to be bound to you under the terms and conditions of the GloboAsia License Agreement; and (ii) Keryx is not in material breach of the Keryx License Agreement.
4. In the event that both the GloboAsia License Agreement and the Keryx License Agreement are terminated prior to expiration, then GloboAsia shall be deemed to have granted to Sublicensee a direct license with respect to the Licensed Patent Property, for Japan, under the terms and conditions of the GloboAsia License Agreement, provided that Sublicensee (i) agrees to be bound to GloboAsia under the terms and conditions of the GloboAsia License Agreement; and (2) Sublicensee is not in material breach of the Japan Sublicense.
5. GloboAsia acknowledges that Sublicensee is relying on the foregoing in entering into the Japan Sublicense and making a substantial investment which will benefit GloboAsia in developing and commercializing products based on the Licensed Patent Property and that, accordingly (i) Sublicensee shall be regarded as a third party beneficiary of this letter agreement entitled to enforce its provisions and (ii) this letter agreement may not be amended, waived, modified or terminated except upon the written agreement of Sublicensee.

Chen Hsing Hsu, M.D.

_____, ___, 2007

Page 3

Please confirm GloboAsia's agreement to the foregoing by signing a copy of this letter and returning it to us.

Very truly yours,

Michael Weiss
Chief Executive Officer

AGREED:

GloboAsia, LLC

By: _____
Keith Chan

Exhibit 6

to Declaration of Beth Levine

From: chank [chank@kitchanlaw.com]
Sent: Friday, September 21, 2007 4:51 PM
To: blevine@keryx.com
Cc: chank
Subject: RE: Dkt #855-PANION - Meeting
Attachments: 859C.doc

Dear Beth,

Further to your e-mail earlier today, I hereby confirm my availability for our meeting on Sunday at 3:00pm. However, what kind of security will be at our meeting? Would I need to bring any documents for security purposes with me?

We are currently working on the patent docket as requested. In regards to the docket you have asked about (Int'l App'l No. PCT/US2006/032385), please see the attached.

We look forward to hearing from you.

Please acknowledge receipt of this e-mail.

Sincerely,

Albert Wai-Kit Chan, Ph.D. /ah
Law Offices of Albert Wai-Kit Chan, PLLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357
Tel: (718) 799-1000
Fax: (718) 357-8615
E-mail: chank@kitchanlaw.com

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From: blevine@keryx.com [mailto:blevine@keryx.com]
Sent: Friday, September 21, 2007 1:13 PM
To: chank
Cc: msw@keryx.com; khberman@keryx.com
Subject: RE: Dkt #855-PANION - Meeting

Dear Albert,

We can make ourselves available for a meeting in our office on Sunday afternoon at 3pm. Michael Weiss and I will participate (though I may only be able to participate by phone) and

we may ask our head of Business Development, Ken Hoberman, to attend as well. Our office is located at 750 Lexington Avenue (entrance is on 59th Street) on the 20th floor.

In advance of the meeting, please forward to us the updated patent docket requested in item 1 of my earlier e-mail.

Please confirm your availability for this meeting.

Thank you.

Beth

From: chank [mailto:chank@kitchanlaw.com]
Sent: Friday, September 21, 2007 12:15 PM
To: Levine, Beth [blevine@keryx.com]
Cc: Weiss, Michael S. [msw@keryx.com]; chank
Subject: RE: Dkt #855-PANION - Meeting

Dear Beth,

Thanks for the email and phone call. Unfortunately, today I am fully booked. Could we meet at your office Sunday afternoon, the 23rd? If yes, please tell me the directions. My Monday schedule is quite "bad as well.

Please acknowledge receipt of this e-mail.

Sincerely,

Albert Wai-Kit Chan, Ph.D.
Law Offices of Albert Wai-Kit Chan, PLLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357
Tel: (718) 799-1000
Fax: (718) 357-8615

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From: blevine@keryx.com [mailto:blevine@keryx.com]
Sent: Friday, September 21, 2007 8:56 AM
To: chank
Cc: msw@keryx.com
Subject: FW: Dkt #855-PANION - telephone call
Importance: High

Mr. Wai-Kit Chan,

My name is Beth Levine and I am General Counsel of Keryx. I understand from an e-mail I received from Michael Chiang that you are now representing Panion in all matters relating to the Keryx/Panion License Agreement (I have attached that e-mail above). I assume, based on this e-mail, that you are now free to speak with us directly. As you will have read from the e-mail from Mr. Chiang, there are several urgent matters outstanding that require immediate attention. I would like to meet with you today to resolve the following matters:

1. We urgently require an updated patent docket. The patent docket that was sent through to us from Panion's prior counsel, Michael Stanley, did not include PCT/US2006/032385. We must have an updated docket today that includes all of the patents and patent applications, as well as any new developments since the last patent docket, which was dated August 30, 2007.
2. We need to obtain signatures from both Panion and GloboAsia on the draft consents that had been previously provided and which are attached again for your reference. The rationale for these documents is explained in the attached e-mail. Based on Michael Chiang's e-mails and representations from Michael Stanley, we assured JT that this was not a problem and that the consents would be signed. They have gone to their Executive Committee with that representation and it would be a great dishonor and embarrassment to our Japanese colleagues if they misrepresent to their Executive Committee, which would consequently seriously jeopardize the relationship and our ability to credibly work with them going forward.

I realize that you have just recently been brought into the business aspects of this matter and I would like the opportunity to discuss this with you in person to resolve any confusion or misunderstandings. Our CEO, Michael Weiss, and I would be happy to come to your office today to meet with you. In fact, Michael also went to Columbia Law School and thought your name sounded familiar. Were you classmates?

I am in the office now and am free to meet with you at any time. Please respond as soon as possible.

Regards, Beth

Beth Levine
Senior Vice President, General Counsel, Chief Compliance Officer & Corporate Secretary
Keryx Biopharmaceuticals, Inc.
750 Lexington Avenue - 20th floor
New York, NY 10022
212-584-5740
212-531-5961 (fax)
blevine@keryx.com

From: Genovesi, Lina [lgenovesi@keryx.com]
Sent: Tuesday, September 18, 2007 3:52 PM
To: Levine, Beth [blevine@keryx.com]
Subject: FW: Dkt #855-PANION - telephone call

See below.

From: chank [mailto:chank@kitchanlaw.com]
Sent: Tuesday, September 18, 2007 3:43 PM
To: Genovesi, Lina [lgenovesi@keryx.com]
Cc: chank
Subject: Dkt #855-PANION - telephone call

Dear Lina,

I understand that you have called my cell phone today requesting to speak with me. Further, I also understand that you tried to reach me at my office today. I am currently asking for permission from my client to speak with you. Unfortunately, until I get permission, my standing instructions are still in force – I cannot speak with anyone from Keryx without instructions.

I apologize for the inconvenience and will attempt to get back to you as soon as possible.

Please acknowledge receipt of this e-mail.

Sincerely,

Albert Wai-Kit Chan, Ph.D. /ah
Law Offices of Albert Wai-Kit Chan, PLLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357
Tel: (718) 799-1000
Fax: (718) 357-8615
E-mail: chank@kitchanlaw.com

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Patent Dkt#859C (CHAN and TOWN, 2006)

DOCKET #	MATTER	NOTE
Dkt. #859-C- PCT	PHARMACEUTICAL-GRADE FERRIC ORGANIC COMPOUNDS, USES THEREOF AND METHODS OF MAKING SAME Int'l App'l No. PCT/US2006/032585, Filed August 18, 2006	PENDING. <ul style="list-style-type: none">■ February 18, 2008: 30 month deadline to file National Stage App'l■ March 18, 2008: 31 month deadline to file National Stage App'l

Inventors: Keith CHAN and Winston TOWN
Applicant: Keith CHAN, Winston TOWN, and
GLOBOASIA, LLC

Exhibit 7

to Declaration of Beth Levine

Exhibit 7

to the Declaration of Beth Levine
has been served on Defendant and,
pursuant to the Court's order dated
November 19, 2007, is being filed
under seal.

Exhibit 8

to Declaration of Beth Levine

From: chank [chank@kitchanlaw.com]
Sent: Wednesday, October 10, 2007 9:24 AM
To: Genovesi, Lina [lgenovesi@keryx.com]
Cc: Levine, Beth [blevine@keryx.com]; Cindy Chiang (PBF); michaelchiang@pbf.com.tw; leehm; chank
Subject: RE: Dkt #1092-PCT-JP: Translated Office Action
Attachments: X1G-0774 English translation of Office Action.doc

Dear Lina,

Further to our telephone conversation this morning, attached is the translated office action.

Please acknowledge receipt of this e-mail.

Sincerely,

Albert Wai-Kit Chan, Ph.D.
Law Offices of Albert Wai-Kit Chan, PLLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357
Tel: (718) 799-1000
Fax: (718) 357-8615

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From: lgenovesi@keryx.com [mailto:lgenovesi@keryx.com]
Sent: Tuesday, October 02, 2007 5:20 PM
To: chank
Cc: blevine@keryx.com; Cindy Chiang (PBF); michaelchiang@pbf.com.tw
Subject: RE: Dkt #1100-A

Received.

Lina Genovesi, PhD, JD
Director of Legal Affairs
Keryx Biopharmaceuticals, Inc.
750 Lexington Avenue, 20th Floor
New York, New York 10022
Phone: (212) 531-5968
Fax: (212) 531-5961
lgenovesi@keryx.com
<http://www.keryx.com>

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From: chank [mailto:chank@kitchanlaw.com]
Sent: Tuesday, October 02, 2007 5:20 PM
To: Genovesi, Lina [lgenovesi@keryx.com]
Cc: Levine, Beth [blevine@keryx.com]; Cindy Chiang (PBF); michaelchiang@pbf.com.tw; chank
Subject: Dkt #1100-A

Dear Lina,

Further to our earlier e-mail, here is my proposed Agenda for our meeting tomorrow:

1. Dkt #859-A-PCT-US: Response to Restriction Requirement
2. Dkt #1092-Z-PCT-JP: New amended claims needed; For your convenience, we hereby attach a copy of the pending claims for your review.
3. Dkt #1092-PCT-JP: Response to Office Action – Although a response is due, we will not have a English translation of the Office Action for about another week. I propose that we discuss this Office Action once we receive it

If you have any questions or have anything else you would like to add to my proposed agenda, please feel free to contact us. In the meantime, I look forward to speaking with you tomorrow.

Please acknowledge receipt of this e-mail.

Sincerely,

Albert Wai-Kit Chan, Ph.D. /ah
Law Offices of Albert Wai-Kit Chan, PLLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357
Tel: (718) 799-1000
Fax: (718) 357-8615
E-mail: chank@kitchanlaw.com

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From: chank
Sent: Tuesday, October 02, 2007 9:52 AM
To: ['lgenovesi@keryx.com'](mailto:lgenovesi@keryx.com)
Cc: ['blevine@keryx.com'](mailto:blevine@keryx.com); ['Cindy Chiang \(PBF\)'](mailto:cychiang@pbf.com.tw); ['michaelchiang@pbf.com.tw'](mailto:michaelchiang@pbf.com.tw); chank
Subject: Dkt #859-A-PCT-US - October 24, 2007

Dear Lina,

Let us discuss this September 24 Office Action tomorrow, the 3rd, at 10 am. For your convenience, attached is the previous office action and our response.

Please acknowledge receipt of this e-mail.

Sincerely,

Albert Wai-Kit Chan, Ph.D.
Law Offices of Albert Wai-Kit Chan, PLLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357
Tel: (718) 799-1000
Fax: (718) 357-8615

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English translation of Japanese Office Action dated August 28, 2007
(Japanese Patent Application No. 10-527705)

Office Action

Cited Reference

1. KURODA, S. et al, Nippon Jinzo Gakkai Shi (Jpn J Nephrol), 1995, Vol.37, No.8, P.468-473 (D1)
2. MEYER, J. L. et al., Trace metal-citric acid complexes as inhibitors of calcification and crystal growth. I. Effects of Fe(III), Cr(III) and Al(III) complexes on calcium phosphate crystal growth, J Urol, 1982, Vol.128, No.6, p.1372-1375 (D2)
3. THOMAS, W.C., Trace metal-citric acid complexes as inhibitors of calcification and crystal formation, Proc Soc Exp Biol Med, 1982, Vol.170, No.3, p.321-327 (D3)

Reason 1. The present application is rejected for the reason that the inventions set out in claims 1 and 2 are identical with the invention disclosed in the publications listed above (D1-D3) which were published prior to the priority date of the present application.

Reason 2. The present application is rejected for the reason that the invention set out in claims 1 and 2 are obvious from the above listed references (D2 and D3) which were published prior to the priority date of the present application..

Examiner's Comments:

Reason 2

D1 describes that sodium iron citrate functions as a phosphate binder and ingestion of the compound is useful for treating hyperphosphatemia, but the ionic charge number of the iron ion composing the compound differs from that of the present invention.

However D1 also describes that ferric salts are most potent in phosphate-binding effect as compared to salts of other metal ions, and it had

been well known that ferric salts reduce plasma phosphate concentration, as described in the present specification. Furthermore D2 and D3 suggest that ferric citrate could be used as pharmaceuticals. Those skilled in the art therefore could easily confirm the inhibitory effects of ferric citrates on absorption of ingested phosphates and formulate ferric citrates to a pharmaceutical composition.

Reasons 1 and 2

D2 and D3 describes that ferric citrate inhibit the calcification and calcium phosphate crystal growth and that ferric citrate is useful for preventing urolithiasis or calculi in various area.

D2 and D3 do not disclose inhibitory effects of ferric citrate on absorption of ingested phosphates. However, since the present invention is used for preventing diseases which are specifically described in page 1 of the specification (page 1 of WO 98/26776), the invention of claim 1 and the inventions described in D2 and D3 could not be distinguished each other as an invention relating to medical use of a composition, because they use the same ingredient for the same diseases.

Furthermore, those skilled in the art would select appropriate administration route and a dose for one administration. Additionally, iron-ion based pharmaceutical composition is conventionally administered through oral route. Thus it is not admitted that there is any significance derived from these specified aspects.

Redacted

Exhibit 9

to Declaration of Beth Levine

Exhibit 9

to the Declaration of Beth Levine
has been served on Defendant and,
pursuant to the Court's order dated
November 19, 2007, is being filed
under seal.

Exhibit 10

to Declaration of Beth Levine

Exhibit 10

to the Declaration of Beth Levine
has been served on Defendant and,
pursuant to the Court's order dated
November 19, 2007, is being filed
under seal.

Exhibit 11

to Declaration of Beth Levine

From: chank [chank@kitchanlaw.com]
Sent: Thursday, October 11, 2007 5:58 PM
To: chem@nakapat.gr.jp
Cc: chank; Levine, Beth [blevine@keryx.com]; Cindy Chiang (PBF); michaelchiang@pbf.com.tw
Subject: RE: Our Dkt #1092-PCT-JP; your File: X1G-0774

Dear Mr. Toshio TAKIZAWA,

Please note that Mr. Teruo Daito appointed by our sublicensee may contact your office in connection with the above docket. Please advise him on the CONFIDENTIAL issues of the communication. Your office is hereby instructed to discuss with him on the best way to overcome the objections and rejections from the Japanese patent office.

However, please do not file any document with the Japanese patent office unless you have received WRITTEN instructions from this office.

Please acknowledge receipt of this e-mail.

Sincerely,

Albert Wai-Kit Chan, Ph.D.
Law Offices of Albert Wai-Kit Chan, PLLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357
Tel: (718) 799-1000
Fax: (718) 357-8615

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Exhibit 12

to Declaration of Beth Levine

Exhibit 12

to the Declaration of Beth Levine
has been served on Defendant and,
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Exhibit 13

to Declaration of Beth Levine

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November 19, 2007, is being filed
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Exhibit 14

to Declaration of Beth Levine

Exhibit 14

to the Declaration of Beth Levine
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pursuant to the Court's order dated
November 19, 2007, is being filed
under seal.

Exhibit 15

to Declaration of Beth Levine

Exhibit 15

to the Declaration of Beth Levine
has been served on Defendant and,
pursuant to the Court's order dated
November 19, 2007, is being filed
under seal.

Exhibit 16

to Declaration of Beth Levine

Exhibit 16

to the Declaration of Beth Levine
has been served on Defendant and,
pursuant to the Court's order dated
November 19, 2007, is being filed
under seal.

Exhibit 17

to Declaration of Beth Levine

Exhibit 17

to the Declaration of Beth Levine
has been served on Defendant and,
pursuant to the Court's order dated
November 19, 2007, is being filed
under seal.

Exhibit 18
to Declaration of Beth Levine

Exhibit 18

to the Declaration of Beth Levine
has been served on Defendant and,
pursuant to the Court's order dated
November 19, 2007, is being filed
under seal.

Exhibit 19

to Declaration of Beth Levine

Exhibit 19

to the Declaration of Beth Levine
has been served on Defendant and,
pursuant to the Court's order dated
November 19, 2007, is being filed
under seal.

Exhibit 20

to Declaration of Beth Levine

Exhibit 20

to the Declaration of Beth Levine
has been served on Defendant and,
pursuant to the Court's order dated
November 19, 2007, is being filed
under seal.

Exhibit 21

to Declaration of Beth Levine

From: blevine@keryx.com
Sent: Saturday, November 17, 2007 3:52 PM
To: blevine@keryx.com; Inubushi, Yoshinori; Kamiya, Takashi; neal.beaton@hklaw.com; Koseki, Koshi
Cc: msw@keryx.com; khberman@keryx.com; lgenovesi@keryx.com
Subject: RE: Response to Panion

Dear Koseki-san,

I am writing today to ask for your assistance on the Japanese Patent Office matter. In light of the Complaint that we filed yesterday, it is difficult to predict how Panion will act with respect to the request for an extension of time to respond to the Office Action. While we are continuing to approach Mr. Chan directly to persuade him to seek the extension, given the short amount of time remaining I think we ought to be prepared as well for a substantive response on November 28th (in the event that Panion does not agree to seek the extension). In that regard, I would like to ask you for the following:

1. Your substantive comments on the draft response prepared by Mr. Chan, which was sent to you in October. I do not have a draft of that response handy, but if you do not have a copy I can send you one on Monday morning. I would like to send Mr. Chan a set of substantive comments on the draft response so they have the benefit of our input if they intend to submit a substantive response.
2. I'd appreciate it if you could collect and summarize any articles and references that have already been analyzed that you believe should be submitted to the Patent Office. I realize that you have not had sufficient time to complete the analysis, but I think we should be prepared to submit as much as we can on the 28th if necessary. I would like to send this summary to Mr. Chan as well for inclusion in the response.

Again, I will continue to press for an extension of time, but I cannot count on Panion responding in a reasonable fashion. Thus, I want to make sure that we are prepared to make the best possible submission on the 28th if the extension is not forthcoming.

Thank you in advance for your help and understanding.

Best regards, Beth

Exhibit 22

to Declaration of Beth Levine

From: Koseki, Koshi [koshi.koseki@lms.jti.co.jp]
Sent: Monday, November 19, 2007 4:29 AM
To: Levine, Beth [blevine@keryx.com]; Inubushi, Yoshinori; Kamiya, Takashi;
neal.beaton@hkklaw.com
Cc: Weiss, Michael S. [msw@keryx.com]; Hoberman, Ken [khoberman@keryx.com]; Genovesi,
Lina [lgenovesi@keryx.com]
Subject: RE: Response to Panion; correspondense part 1

Redacted

Dear Levine-san,

Thank you for update information.

Attached, please find six articles selected from our preliminary search result which may be used in a possible counter argument. I am afraid this is JT's best to assist your discussion. I am regretful that we had no time to analyze them fully, not shared with our counsel yet, and that we would not be prepared in such a short time to make a substantive recommendation.

In the initial meeting at Nakamura Office, it was recognized that understanding of background of the technology was essential. Extensive search was planned and conducted in view of three months extension. Any element of our planned work has not been completed.

Also, I would like to ask you for your kind understanding about my difficulty for your request. We may be able to make extensive analysis and discussion only in face to face to establish logic of counter argument because the background of the technology is so broad.

However the status is, I hope these materials may help your discussion with Panion, Mr. Chan. I apologize for three documents in Japanese, I did not eliminate them as I hope translation assist may be available on your end.

Best regards,

Koseki, Koshi

Redacted

Exhibit 23

to Declaration of Beth Levine

From: Koseki, Koshi [koshi.koseki@ims.jti.co.jp]
Sent: Monday, November 19, 2007 4:32 AM
To: Levine, Beth [blevine@keryx.com]; Inubushi, Yoshinori; Kamiya, Takashi;
neal.beaton@hklaw.com
Cc: Weiss, Michael S. [msw@keryx.com]; Hoberman, Ken [khoberman@keryx.com]; Genovesi,
Lina [lgenovesi@keryx.com]
Subject: RE: Response to Panion; correspondence part 2

Redacted

Dear Levine-san,

Thank you for update information.

Attached, please find six articles selected from our preliminary search result which may be used in a possible counter argument. I am afraid this is JT's best to assist your discussion. I am regretful that we had no time to analyze them fully, not shared with our counsel yet, and that we would not be prepared in such a short time to make a substantive recommendation.

In the initial meeting at Nakamura Office, it was recognized that understanding of background of the technology was essential. Extensive search was planned and conducted in view of three months extension. Any element of our planned work has not been completed.

Also, I would like to ask you for your kind understanding about my difficulty for your request. We may be able to make extensive analysis and discussion only in face to face to establish logic of counter argument because the background of the technology is so broad.

However the status is, I hope these materials may help your discussion with Panion, Mr. Chan. I apologize for three documents in Japanese, I did not eliminate them as I hope translation assist may be available on your end.

Best regards,

Koseki, Koshi

Redacted

Exhibit 24

to Declaration of Beth Levine

From: Levine, Beth [blevine@keryx.com]
Sent: Monday, November 19, 2007 11:57 AM
To: chank
Cc: Genovesi, Lina [lgenovesi@keryx.com]
Subject: Japanese Patent Prosecution
Attachments:

~~Redacted~~

Dear Kit,

Because of Panion's unjustified refusal to request an extension of time from the Japanese Patent Office to respond to the Notice of Office Action, I have asked our colleagues in Japan to send the partially complete results of their reference search and analysis to date. They have requested more time to complete their analysis, which is time consuming and labor intensive if done correctly and professionally. Attached you will find six references that have been identified as potentially useful in responding to the Office Action. Consistent with your obligations under the License Agreement, you must give due consideration to this input.

However, it is critical that you understand that the search undertaken by the Japanese patent attorneys after meeting with Panion's counsel in Japan has not yet been completed. There are likely additional references and analyses that would be persuasive to the patent examiner. Without the extension, we will be unable to gather and analyze these materials.

We have shared with you detailed information on the scope and status of the reference search and you have nonetheless refused to seek an extension. Your rejection of our reasonable request (particularly in light of our offer to bear any expenses associated with the extension) smacks of willful misconduct and places undue risk on the likelihood that a patent will issue in Japan. To ensure that we have an opportunity to submit our best defense of the patent application, we demand that you seek an extension of time to respond to the Notice of Office Action.

Regards, Beth

Beth Levine
Senior Vice President, General Counsel, Chief Compliance Officer & Corporate Secretary
Keryx Biopharmaceuticals, Inc.
750 Lexington Avenue - 20th floor
New York, NY 10022
212-584-5740
212-531-5961 (fax)
blevine@keryx.com